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Remarks

Claims 46 and 48-51 were examined and rejected in the Office Action of August 26, 2003. With this Reply, applicants amend claims 46 and 51, and add claim 52, to more particularly point out and distinctly claim the invention.

Drawing Objections

Figures 3 and 5 are objected to for having ambiguous reference characters. Applicants have provided new Figures 3-6, where Figure 5 as filed is deleted, Figure 6 as filed is renamed Figure 5, and Figure 7 as filed is renamed Figure 6. Applicants believe that the cancellation of Figure 5, and the provision of a corrected Figure 3 resolve the current objections. Withdrawal of those objections is therefore respectfully requested.

Claim Objection

Claim 51 is objected to for not beginning with a capital letter. Applicants note that the amended claim 51 begins with a capital letter. Accordingly, applicants respectfully request withdrawal of the objection to claim 51.

Rejections under 35 U.S.C. 112, first paragraph

Claims 46 and 48-51 stand rejected under 35 U.S.C. 112, first paragraph, as not being enabled for all *iniB* promoters of all origins. Applicants respectfully request reconsideration and withdrawal of this rejection based on the claim amendments and the following discussion. Claim 46, as amended, is limited to the use of a *Mycobacterium tuberculosis* *iniB* promoter and not all *iniB* promoters. The specification provides an enabling disclosure for the use of an *M. tuberculosis* *iniB* promoter, as confirmed in the Office Action in the context of the current rejection (Item 10, on page3). Accordingly,

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applicants respectfully request withdrawal of the current rejection under 35 U.S.C. 112, first paragraph.

Rejections under 35 U.S.C. 112, second paragraph

Claims 46 and 48-51 stand rejected under 35 U.S.C. 112, second paragraph, as having insufficient antecedent basis for the limitation “the” *iniB* promoter, as recited in claim 46. Applicants note that claim 46 as amended does provide proper antecedent basis for all claim terms. Withdrawal of the rejection of claims 46 and 48-51 under 35 U.S.C. 112, second paragraph, is therefore respectfully requested.

Claim 46, 48 and 51 also stand rejected under 35 U.S.C. 112, second paragraph as being incomplete for omitting essential steps, amounting to a gap between the steps. The PTO asserts that claim 46 omits 1) how one actually measures the induction of the *iniB* promoter, and 2) correlation of induction with effectiveness against *M. tuberculosis*. Applicants respectfully request reconsideration and withdrawal of this rejection based on the following discussion.

With regard to the assertion that the method of measurement of induction of the *iniB* promoter is an omitted essential step, applicants disagree that the particular method of measuring induction is an essential step that is required to be in claim 46 to have a complete claim. The PTO cites MPEP 2172.01 as justification for this rejection. However, MPEP 2172.01 states that only matter disclosed to be essential to the invention as described in the specification must be present in a claim. In this case, the specification does not indicate that any particular method of measuring induction of the *iniB* promoter is essential. Indeed, the specification indicates the opposite, by stating only that “[i]nduction is preferably determined by the expression of a reporter gene,”

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Specification at page 14, lines 26-27. It is well established that features which are preferred are not to be considered critical. See *In re Goffe*, 191 USPQ 429, 431 (CCPA 1976) (“To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for ‘preferred’ materials . . . would not serve the constitutional purpose of promoting progress in the useful arts.”). This is further elaborated in MPEP 2164.08(c). In the present case, the specification only provides that the use of a reporter gene is preferred, not critical. Additionally, the skilled artisan, would understand that many methods exist for the measurement of induction of a promoter, and the novelty of the instant invention is not dependent on the use of any particular method for measuring induction of an *iniB* promoter.

With regard to the assertion that claim 46 does not correlate induction of *iniB* with effectiveness against *M. tuberculosis*, applicants disagree, since step (d) of claim 46 clearly states, “. . . the presence of induction indicating the drug is effective against *Mycobacterium tuberculosis*.”

In light of the above discussion, applicants respectfully request withdrawal of the current rejections of claims 46, 48 and 51 under 35 U.S.C. 112, second paragraph.

Conclusion

Based on the claim amendments and the above discussion, applicants respectfully request withdrawal of all rejections and allowance of claims 46 and 48-52. If there are any minor matters preventing the allowance of the currently pending claims as amended, applicants request that Examiner Swartz contact the undersigned attorney.


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Applicants believe that no fee is required with this Reply. Authorization is hereby given to charge any unanticipated fee deficiency to Deposit Account No. 01-1785.

Respectfully submitted,

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